ELabELN

Template Use Case White Paper

qPCR Experiment Template

Structured Documentation for Quantitative PCR from Reagent Thaw Through ΔΔCt Analysis

Applies to:

- Academic and life sciences research laboratories
- Biotechnology and pharmaceutical R&D groups
- Contract research organizations (CROs)
- Diagnostic and clinical development labs

Relevant compliance frameworks:

- FDA 21 CFR Part 11 — Electronic records and signatures
- GAMP 5 — Software validation for regulated industries
- ICH E6 (R2) — Good Clinical Practice documentation
- NIH / NSF grant reproducibility requirements

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1. Executive Summary

Quantitative PCR (qPCR) is among the highest-frequency molecular biology techniques performed in life sciences laboratories today. Yet most labs still document their qPCR runs in paper notebooks, spreadsheets, or loosely structured word processing files — approaches that introduce transcription errors, obscure lot traceability, and make results difficult to retrieve or audit after the fact.

The ELabELN qPCR Experiment Template solves this by providing a pre-built, fully structured experiment record that loads in a single click. It ships with a 10-step workflow checklist, validated reagent and primer references, structured fields for all cycling parameters and Ct thresholds, a 96-well plate layout pre-configured for technical triplicates, and pre-wired links to SOPs and upstream reverse transcription experiments. Every check-off is timestamped to the system audit trail, and every signature is electronically captured in a format designed to support FDA 21 CFR Part 11 review.

This white paper describes what the template contains, the experimental use case it is designed to support, the broader workflows it connects to, and how a laboratory can deploy and begin using it within days.

KEY BENEFIT

Labs that adopt the ELabELN qPCR template report eliminating manual Ct transcription steps, gaining immediate cross-experiment searchability on sample and target metadata, and producing audit-ready records without additional post-run documentation effort.

2. What is qPCR and Why Does Documentation Matter?

2.1 The Technique

Quantitative polymerase chain reaction (qPCR) measures the quantity of a specific nucleic acid sequence in a sample by monitoring fluorescence signal in real time as PCR amplification proceeds. The cycle threshold (Ct) — the cycle number at which fluorescence crosses a defined threshold — is inversely proportional to the starting quantity of target sequence. By comparing Ct values for a gene of interest against a reference housekeeping gene (such as GAPDH or ACTB), researchers calculate relative expression changes using the ΔΔCt method.

qPCR is foundational to gene expression analysis, biomarker quantification, pathogen detection, copy number variation studies, and validation of RNA interference or CRISPR editing experiments. Its sensitivity and dynamic range make it the gold standard for quantifying low-abundance transcripts, but that same sensitivity demands rigorous documentation: small errors in reagent lot, reaction volume, cycling temperature, or reference gene selection can shift results by orders of magnitude.

2.2 The Documentation Problem

A typical qPCR run involves dozens of discrete decisions and data points. Documenting this in a paper notebook or spreadsheet creates several interconnected risks:

- Transcription errors when copying Ct values from instrument software to a spreadsheet
- Missing lot number records for reagents or primers that expire or are recalled
- No link between the qPCR record and the upstream RT experiment that produced the cDNA
- Inability to find prior runs by sample, target, or cell line without manually reviewing notebooks
- No timestamped evidence of who performed each step and when
- Non-compliance with grant or regulatory requirements for reproducible, auditable records

These are not hypothetical risks. Replication failures in molecular biology are frequently traced to underdocumented or inconsistently documented experimental procedures. The ELabELN qPCR template was designed specifically to close these gaps.

3. Template Overview: What Ships with the Template

The ELabELN qPCR Experiment Template is a pre-populated experiment record available to all ELabELN subscribers directly from the template library. It is configured for standard SYBR Green chemistry on a QuantStudio 5 running a two-target ΔΔCt comparison between HER2 and GAPDH primer pairs in HeLa and SK-BR-3 cell line models. Every section is editable — the configuration is a tested baseline, not a locked format.

3.1 Template Sections at a Glance

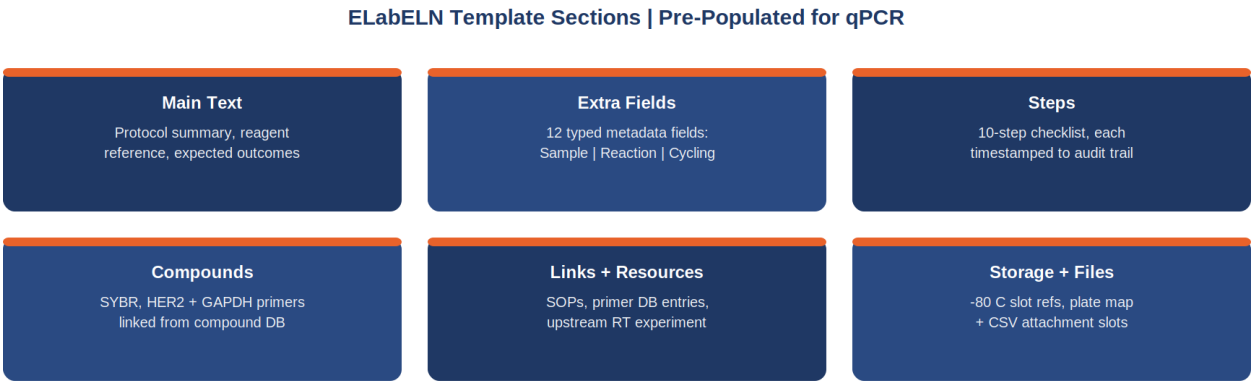
ELabELN Template Sections | Pre-Populated for qPCR
Main Text
Protocol summary, reagent reference, expected outcomes
Extra Fields
12 typed metadata fields: Sample | Reaction | Cycling
Steps
10-step checklist, each timestamped to audit trail
Compounds
SYBR, HER2 + GAPDH primers linked from compound DB
Links + Resources
SOPs, primer DB entries, upstream RT experiment
Storage + Files
-80 C slot refs, plate map + CSV attachment slots

Figure 1. The six ELabELN experiment sections pre-populated by the qPCR template.

Section	What It Pre-Populates
Main Text	Protocol summary, reagent reference list with lot fields, expected outcomes, and links to RT prep SOPs — authored in the TinyMCE rich text editor
Extra Fields	Twelve structured, typed metadata fields organized into three groups: Sample (cell line, target gene, reference gene, biological replicate), Reaction (master mix volume, primer concentration, template input), and Cycling (annealing temperature, extension time, cycle count, melt curve, Ct threshold)
Steps	Ten-step workflow checklist covering reagent thaw through ΔΔCt analysis — each step is ticked off in real time and the timestamp is written to the audit trail automatically
Compounds	SYBR Green Master Mix, HER2 primer pair, and GAPDH primer pair pre-linked from the compound/reagent database — lot numbers and stock status flow into the record automatically
Links & Resources	Pre-wired references to qPCR Setup SOP v3.2, HER2 and GAPDH primer database entries, and the upstream RT experiment that produced the cDNA input
Storage & Files	Freezer slot references for cDNA stocks and master-mix aliquots at −80 °C; labelled attachment slots for the plate map image and the instrument's raw CSV/RDML export

3.2 The Ten-Step Protocol

The workflow checklist is the operational spine of the template. Each step maps to a discrete laboratory action and drives a timestamped audit trail entry when checked off.

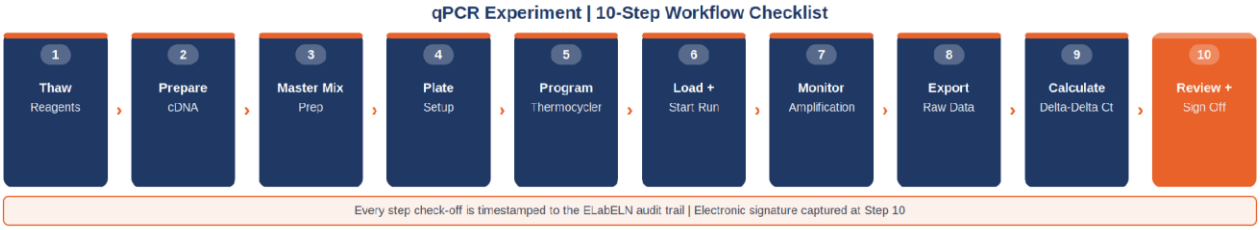

Figure 2. The 10-step qPCR workflow checklist — every check-off writes a timestamped entry to the ELabELN audit trail.

Step	Action	What ELabELN Captures
1	**Thaw & Prepare Reagents**	Timestamp, operator ID, lot numbers confirmed against compound DB
2	**Prepare cDNA from Stock**	Stock ID, dilution factor, template concentration entered into Extra Fields
3	**Master Mix Preparation**	Volume, component lots auto-linked from compound records
4	**Set Up Reaction Plate**	Plate layout image attached; well assignments documented
5	**Program the Thermocycler**	Cycling parameters populated from Extra Fields; instrument ID logged
6	**Load Plate & Start Run**	Instrument load timestamp captured; run file attachment slot activated
7	**Monitor Amplification**	Any mid-run notes logged inline; melt curve parameters confirmed
8	**Export & Attach Raw Data**	CSV/RDML file attached; export timestamp logged to audit trail
9	**Calculate ΔΔCt Values**	Ct values entered into structured fields; analysis notes captured
10	**Review & Sign Off**	PI or supervisor electronic signature captured under 21 CFR Part 11

4. Use Cases: When to Reach for This Template

The template ships pre-configured for a specific assay — HER2 expression analysis by ΔΔCt in breast cancer cell lines — but the underlying structure is applicable to any two-target relative quantification experiment. The following use cases represent the primary scenarios in which laboratories reach for this template.

4.1 Gene Expression Analysis (Primary Use Case)

The core design scenario: a researcher wants to compare the relative expression of a target gene between two or more sample groups, normalized to a stable reference gene. The template's 12 structured Extra Fields, 96-well plate layout, and ΔΔCt calculation scaffold are all built for this workflow. Swap the cell lines, swap the gene targets, adjust primer concentrations, and the structural logic remains intact.

TYPICAL APPLICATIONS

HER2/ERBB2 expression in breast cancer cell lines (template default)
Cytokine gene expression (IL-6, TNF-α, IFN-γ) in immune activation studies
Differentiation marker quantification in stem cell research
Drug target modulation in small-molecule screening follow-up

4.2 CRISPR and RNAi Validation

After a CRISPR knockout or siRNA knockdown experiment, the investigator must confirm that the target gene transcript is reduced at the mRNA level. This template provides the structured ΔΔCt workflow and the upstream RT experiment link that are essential for documenting editing efficiency. The audit trail supports IP notebooks and grant reporting requirements.

4.3 Biomarker Quantification in Translational Research

Translational teams running qPCR on patient-derived samples require records that connect the sample's clinical metadata to the molecular result. The ELabELN template's structured fields and compound database links provide the traceability layer; the electronic signature step provides the sign-off record required for studies approaching regulatory submission.

4.4 QC Testing and Lot Release in Regulated Labs

Pharmaceutical QC and biologics manufacturing labs running qPCR for identity testing, mycoplasma detection, or viral clearance validation require records that satisfy FDA 21 CFR Part 11. The template's tamper-evident audit trail, electronic signature step, and structured fields produce a record that can be directly attached to a batch record or validation report without additional post-run documentation.

4.5 Multi-Lab and CRO Settings

Contract research organizations running qPCR assays for multiple clients need per-study isolation, version-controlled protocols, and client-deliverable reports. ELabELN's project and team permission model, combined with this template's pre-wired SOP links and step-level audit trail, allows a CRO to enforce consistent documentation standards across all client studies without per-seat licensing costs — every ELabELN edition includes unlimited users.

5. Dependencies and Connected Workflows

The qPCR template does not exist in isolation. It sits inside a network of connected laboratory workflows — some upstream, some downstream, some parallel — that give the template record its full scientific and regulatory value.

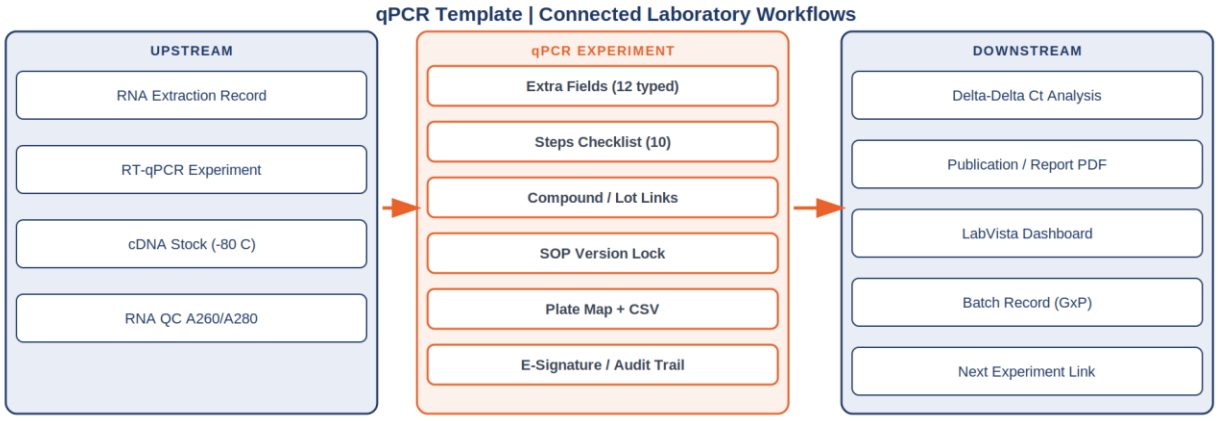

Figure 3. The qPCR template connects upstream sample preparation, parallel inventory and SOP systems, and downstream analytics and reporting workflows.

5.1 Upstream: RNA Extraction and Reverse Transcription

qPCR measures cDNA produced by reverse transcription (RT) of RNA. The ELabELN qPCR template ships with a pre-wired link to the upstream RT experiment record. When a researcher opens the template, the linked RT experiment provides:

- RNA concentration and A260/A280 purity ratio from the source extraction record
- RT reaction conditions and reverse transcriptase lot number
- cDNA stock identifier and storage location for the exact aliquot used
- Timestamp and operator identity from the RT run

This linkage means the qPCR result is traceable all the way back to the RNA source without any manual cross-referencing.

5.2 Parallel: Inventory and Reagent Management

The Compounds section links reagents directly to the ELabELN inventory. When a technician opens the experiment, ELabELN checks whether each linked reagent is in stock and displays its current lot number, expiration date, and storage location. If a reagent is low in stock, a warning appears before the run begins. Lot information flows into the experiment record automatically — no manual transcription from a tube label.

5.3 Parallel: SOP Version Control

The template links to a specific version of the qPCR Setup SOP. If the SOP is updated between runs, ELabELN tracks which version of the SOP was in force at the time of each experiment. This prevents the ambiguity of “which protocol version did we follow?” that arises in paper-based systems.

5.4 Downstream: Data Analysis and Reporting

- **ΔΔCt analysis:** The structured Ct fields allow query-based retrieval of all Ct values for a given target and reference across all experiments in the system.
- **Publication and report generation:** ELabELN experiment records can be exported as PDF with full metadata, audit trail, and attached data files.
- **LabVista dashboards (ELabELN Suite):** Teams using the ELabELN Suite can connect LabVista to pull structured qPCR metadata into dashboards showing expression trend data, inter-assay Ct variability, and reagent usage across a research program.
- **LabVia instrument integration (ELabELN Suite):** Labs with QuantStudio or other supported instruments can configure LabVia to push cycling run data directly into the experiment record.

5.5 Regulatory and Compliance Context

For labs operating under FDA 21 CFR Part 11, the template-driven workflow provides:

- Audit trail entries for every step check-off, field edit, and file attachment
- Electronic signature with user authentication, date, and meaning of signature
- Tamper-evident record storage — any post-signature edit creates a new audit event
- System-level access controls on who can sign off versus who can only view

6. How Scientists Benefit

The practical benefits of the qPCR template divide into four categories: time savings, data quality, compliance readiness, and institutional knowledge retention.

6.1 Time Savings

Without the Template	With the ELabELN qPCR Template
Build a new spreadsheet or notebook page for each run	Open template → instance created in one click
Manually copy Ct values from instrument display	Attach raw CSV → structured fields capture key values
Write protocol steps from memory or a separate document	10-step checklist pre-written and version-controlled
Manually record reagent lot numbers from tube labels	Compound DB link pulls lots automatically
Manually link back to the RT experiment used	Upstream link pre-wired in the template
Compile report after the run with all the above	Export directly from ELabELN as a formatted PDF

6.2 Data Quality and Reproducibility

Structured fields prevent the ambiguity that free-text documentation creates. When Ct threshold is a typed number field with a validated range rather than a sentence in a paragraph, it is machine-readable, queryable, and comparable across experiments. Cross-experiment comparison becomes straightforward rather than requiring manual harmonization.

6.3 Compliance and Auditability

The ELabELN qPCR template produces records that satisfy all four ALCOA criteria:

- **Attributable:** Every entry is linked to the authenticated user who made it.
- **Accurate:** Structured fields with validated ranges prevent out-of-bound values from being saved.
- **Contemporaneous:** Step check-offs are timestamped at the moment they occur.
- **Original:** The system record is the primary record; no transcription from a separate source.

6.4 Knowledge Retention

When qPCR documentation lives in ELabELN with a structured template, the methodology, reagent choices, and prior results are searchable by anyone with appropriate access, regardless of who ran the original experiments. New lab members can review every prior qPCR run and build on established protocols without starting from zero.

7. Plate Layout and Structured Data Fields

The template ships with two of its most distinctive structural elements pre-configured: a 96-well plate layout for the HER2/GAPDH ΔΔCt assay, and 12 typed Extra Fields that make all run metadata queryable across the entire experiment library.

7.1 96-Well Plate Layout

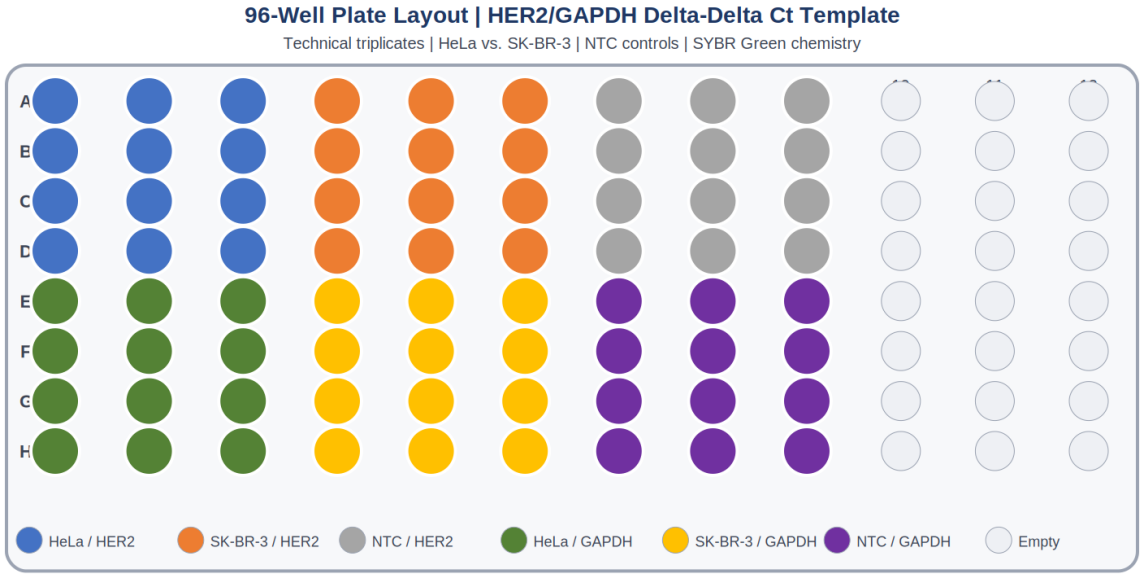

Figure 4. The template's default 96-well plate layout: HER2 and GAPDH primer rows, HeLa and SK-BR-3 cell lines in technical triplicates, with NTC controls. Fully editable for any assay configuration.

The default layout supports technical triplicates for both HER2 and GAPDH primer pairs across HeLa and SK-BR-3 cell lines, with no-template control (NTC) wells per primer set. Columns 10–12 are left unassigned for lab-specific additions. Swap cell lines, add targets, or restructure the plate entirely — then attach the updated layout image to the experiment record.

7.2 Delta-Delta Ct Data Flow

Once the run is complete and Ct values are entered into the structured Extra Fields, ELabELN connects that data to every downstream workflow automatically.

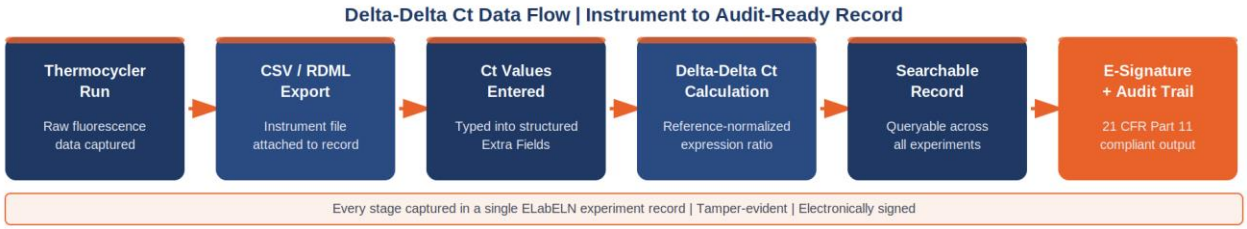
Delta-Delta Ct Data Flow | Instrument to Audit-Ready Record
Thermocycler Run
Raw fluorescence data captured
CSV / RDML Export
Instrument file attached to record
Ct Values Entered
Typed into structured Extra Fields
Delta-Delta Ct Calculation
Reference-normalized expression ratio
Searchable Record
Queryable across all experiments
E-Signature + Audit Trail
21 CFR Part 11 compliant output
Every stage captured in a single ELabELN experiment record | Tamper-evident | Electronically signed

Figure 5. The ΔΔCt data flow from thermocycler run through audit-ready ELabELN record — every stage captured in a single structured experiment.

8. Configuring the Template for Your Assay

The template ships pre-configured for HER2/GAPDH ΔΔCt analysis in HeLa and SK-BR-3 cell lines on SYBR Green chemistry. Adapting it to a different assay is a matter of editing the relevant sections — not rebuilding the structure.

8.1 Swapping Cell Lines or Sample Types

Edit the 'Cell Line / Sample Type' Extra Field to reflect the samples your lab actually uses. The field accepts free text, accommodating anything from a cell line name to a patient sample identifier or tissue type.

8.2 Changing Target and Reference Genes

Replace the HER2 primer entries in the Compounds section with your target gene primers. Replace the GAPDH entry with your reference gene of choice (ACTB, B2M, HPRT1, etc.). If your primers are already in the ELabELN compound database, simply re-link them.

8.3 Adapting Cycling Parameters

The cycling Extra Fields capture annealing temperature, extension time, and cycle number as typed numeric fields. Edit these to match your assay's optimized cycling program. The structure accommodates both SYBR Green and TaqMan probe chemistry.

8.4 Saving a Custom Version

Once configured, save it as a private template scoped to your team. Every subsequent run of that assay opens from your configured version. Separate template versions can be maintained for different assays, instruments, or regulatory contexts.

9. Getting Started

Deploying the qPCR template in your lab follows a straightforward path. ELabELN Standard is a cloud-hosted SaaS deployment typically live within one to two business days of account creation.

9.1 Deployment Path

1. **Start an ELabELN account:** Visit elabeln.com/get-started. ELabELN Standard runs on sciCloud.net, LabLynx's managed cloud infrastructure. No hardware, no IT project, no per-seat licensing.
2. **Provision your instance:** LabLynx provisions the instance within one to two business days. You receive a URL, admin credentials, and onboarding documentation.
3. **Load the qPCR template:** From the ELabELN template library, search for 'qPCR Experiment' and click 'Use This Template.' An editable instance opens immediately.
4. **Add your reagents to the compound database:** Enter your master mix, target primers, and reference primers with lot numbers and storage locations. This is a one-time setup step.
5. **Link your SOPs:** Upload your qPCR setup SOP to ELabELN and connect it to the template's Links section.
6. **Customize the template for your assay:** Edit the Extra Fields, cycling parameters, cell line / sample type fields, and plate layout. Save as a private team template.
7. **Run your first experiment:** Open your saved template, complete the 10-step checklist, attach your data file, and have the PI sign off electronically.

TYPICAL TIMELINE

Day 1: Account request submitted at elabeln.com/get-started
Day 2-3: Instance provisioned; compound database populated; SOPs uploaded
Day 3-4: Template configured and saved as private version for your assay
Day 4-5: First live run documented in ELabELN with audit trail and e-signature

9.2 ELabELN Standard vs. ELabELN Suite

Capability	Standard	Suite
qPCR template access	✓ Included	✓ Included
Unlimited users	✓ Included	✓ Included
Audit trail and e-signatures	✓ Included	✓ Included
Compound/reagent database	✓ Included	✓ Included
SOP linking and version control	✓ Included	✓ Included
LabDrive file metadata search	—	✓ Suite add-on
LabVia instrument data capture	—	✓ Suite add-on
LabVista dashboards and analytics	—	✓ Suite add-on
Direct thermocycler data push	—	✓ Via LabVia

10. Frequently Asked Questions

Can I use this template if my lab does not run HER2 assays?

Yes. The HER2/GAPDH configuration is the pre-populated example, not a restriction. Every field, compound link, and step is editable. Configure it for any two-target ΔΔCt comparison — or for absolute quantification, copy number, or pathogen detection assays by adjusting the analysis fields accordingly.

Does the template work with my thermocycler model?

The cycling program is written for standard SYBR Green chemistry on a QuantStudio 5 and is compatible with any instrument that supports an open run protocol. For instruments with proprietary file formats, the ELabELN team can map the export format as part of onboarding. The LabVia instrument integration layer (ELabELN Suite) supports hundreds of instrument profiles for direct data capture.

How is this different from documenting in Excel?

Excel stores values. ELabELN knows what a value means. A Ct value in Excel is a number in a cell with no context. In ELabELN it is a typed field linked to a sample, a target gene, a primer lot, and a run timestamp — queryable across every experiment in the system. Excel has no audit trail, no electronic signature, no SOP version control, and no reagent lot tracking.

Is this template available without an additional fee?

Yes. Every published template in the ELabELN library is included in all subscription tiers — Standard and Suite — at no additional cost. All editions include unlimited users.

Can I use this template for a regulated study?

ELabELN is designed to support FDA 21 CFR Part 11 compliance. The audit trail, electronic signature, and tamper-evident record storage that the template leverages are engineered to that standard. For studies that require a formal validation package (IQ/OQ/PQ), LabLynx provides a complete validation manual and can support the validation engagement.

11. Conclusion

The ELabELN qPCR Experiment Template is not simply a digital version of a paper protocol sheet. It is a structured, audit-ready, searchable experimental record that connects to your reagent inventory, your SOPs, your upstream experiments, and — in the Suite edition — your instruments and analytics dashboards. It turns a high-frequency, documentation-intensive technique into a workflow that is faster to execute, easier to review, and built to survive a regulatory audit or a grant replication request.

For a laboratory that runs qPCR regularly, the benefit compounds quickly: every run produces a record that future researchers can find, understand, and build on without reconstruction. Every reagent lot is traceable. Every protocol version is documented. Every step is timestamped. Every sign-off is authenticated.

The template is available to all ELabELN subscribers today. A new instance is live in one to two days, and the first structured qPCR record is typically complete within a week of account creation.

GET STARTED

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Browse the full template library at elabeln.com/resources/templates/
Call us at 866.522.5969 or email info@lablynx.com with questions.
Pricing details are available at elabeln.com/pricing -- all plans include unlimited users.

About LabLynx, Inc.

LabLynx, Inc. is an Atlanta-based laboratory informatics company with more than 25 years of experience building software for research, quality, and regulated laboratories. ELabELN is LabLynx's electronic lab notebook platform, hosted on sciCloud.net and available as a Standard or Suite edition with unlimited users on every plan.

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